SEP 2 4 1999

K991900

OSBORN GROUP, INC.
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510(k) SUMMARY

Osborn Group, Inc
HemoChek Urine Collection Kit

May 25, 1999

Submitter Information:

Osborn Group, Inc.
19401 West 117th Street
Olathe, Kansas 66062

Submitter's Name: Gilbert P. Bourk III
Phone: (913) 390-7146

Device Name:

Osborn Group, Inc. HemoChek Urine Collection Kit

Common Name: Urine collection kit

Classification Name: Specimen container

Predicate Device Equivalence:

Substantial equivalence is claimed to the Osborn Group, Inc. Oral-Eze™ Oral Fluid Collection System (primary predicate device) and the Sage Products Inc. Midstream Collection Kit , cleared for commercial distribution per K984361and K800947, respectively.

Device Description:

The HemoChek Urine Collection Kit is a device used by a person under the supervision of a trained health care professional to obtain a urine specimen midstream or by dipping the absorbent pad in a cup of urine, contain the specimen, and preserve the specimen after collection and during mailing to the laboratory for testing of creatinine and microalbumin concentrations. The device consists of the following:

- A collector pad holder/handle with a collector pad and a protective cover over the pad, contained in a sealed "peel-apart" plastic envelope. The collector pad holder/ handle itself consists of two parts, a collector pad holder and a collector pad slider. The collector pad is held in the holder/handle by a pin in the slider that fits into a hole in the collector pad, and by the holder, which keeps the pad from falling off the pin. The slider has a round indicator port in it. A blue color appears in this indicator port when a sufficient amount of urine has been collected.
- A Specimen Tube with a screw-on lid, containing preservative fluid.
- A clear plastic sealed envelope that contains both of the above items.

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- A Patient Identification Card which contains the patient's name, address, Social Security Number, Insurance information, the Doctor's name and a bar-coded label which is peeled off and attached to the Collection Tube after the sample has been taken.

- A set of instructions.

- A zip lock bag into which the Specimen Tube is placed after the sample has been taken.

- A mailer into which the zip lock bag is placed.

- A polyethylene mailing envelope which contains all of the above items and is used to mail the HemoChek Urine Collection Kit to the patient.

Intended Use:

The HemoChek Urine Collection Kit is a prescription device intended to collect a urine specimen in midstream, or by dipping the absorbent pad in a cup containing urine, contain the specimen, and preserve the specimen after collection and during mailing from the collection area to the laboratory for testing of creatinine and microalbumin concentrations.

Comparison of Technological Characteristics:

The HemoChek Urine Collection Kit is physically identical to the primary predicate device, the Oral-Eze Oral Fluid Collection Device. The method used to collect a midstream urine specimen is identical to that used by the secondary predicate device, the Sage Products Inc. Midstream Collection Kit.

Summary of Device Testing:

To assess the capability of the HemoChek Urine Collection Kit to obtain a urine specimen that is equivalent to preserved urine, several tests were conducted from the same urine pool, with specimens collected using the HemoChek device and preserved urine. The test results demonstrated that the samples collected with the HemoChek device produce substantially the same results as specimens of preserved and unpreserved urine.

Conclusions:

Based on the above, we have concluded that the HemoChek Urine Collection Kit is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 1999

Mr. Gilbert P. Bourk III
Vice President and General Counsel
Osborn Group, Inc.
14901 West 117th Street
Olathe, Kansas 66062

Re: K991800
Trade Name: HemoChek Urine Collection Kit
Regulatory Class: I
Product Code: JIQ, CGX, FMH
Dated: July 20, 1999
Received: July 21, 1999

Dear Mr. Bourk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OSBORN GROUP, INC.
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Device Name: K991800

HemoChek Urine Collection Kit

Indications for Use:

The HemoChek Urine Collection Kit is a prescription device intended to collect a urine specimen in midstream or by dipping the absorbent pad in a cup containing urine, contain the specimen, and preserve the specimen after collection and during mailing from the collection area to the laboratory for testing of creatinine and microalbumin concentrations.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991800

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